

AMENDED IN SENATE MARCH 29, 2012
AMENDED IN ASSEMBLY JANUARY 13, 2012
AMENDED IN ASSEMBLY JANUARY 4, 2012
AMENDED IN ASSEMBLY MARCH 31, 2011

CALIFORNIA LEGISLATURE—2011–12 REGULAR SESSION

ASSEMBLY BILL

No. 510

Introduced by Assembly Member Bonnie Lowenthal

February 15, 2011

An act to amend Sections 115111, 115112, and 115113 of the Health and Safety Code, relating to public health.

LEGISLATIVE COUNSEL'S DIGEST

AB 510, as amended, Bonnie Lowenthal. Radiation control: health facilities and clinics: records.

Under existing law, the State Department of Public Health licenses and regulates health facilities and clinics, as defined. Under existing law, the Radiation Control Law, the department licenses and regulates persons that use devices or equipment utilizing radioactive materials. Under existing law, the department is authorized to require registration and inspection of sources of ionizing radiation, as defined. Existing law, commencing July 1, 2012, requires that a facility using a computed tomography (CT) X-ray system record the dose of radiation on every CT study produced. Existing law requires that the displayed dose of radiation be verified annually by a medical physicist to ensure the accuracy of the displayed dose unless the facility is accredited. Violations of these provisions are a crime.

This bill would *require the facility to record the dose of radiation on every diagnostic CT study and would exempt* specified CT studies from being required to record the dose. This bill would delete the exemption for accredited facilities and would authorize a facility ~~that has an accredited machine with an accredited CT X-ray system~~ to elect not to annually verify the displayed dose of radiation, as specified. Because accredited facilities could now be subject to these provisions, and because a violation of these provisions is a crime, the bill would impose a state-mandated local program by expanding the scope of a crime. The bill also would require the dose to be verified for the facility's standard adult brain, adult abdomen, and pediatric brain protocols.

Existing law, commencing July 1, 2013, requires facilities that furnish CT X-ray services to be accredited by an approved organization, as specified.

This bill would ~~not require~~ *eliminate the requirement that* the facilities ~~to be accredited, but~~ *and instead would require the CT X-ray systems to be accredited by an approved organization, as specified.*

Existing law, commencing July 1, 2012, requires a facility to report the discovery of certain information about an event in which the administration of radiation results in prescribed occurrences, including the CT X-ray irradiation of an area of the body other than that intended, within 5 business days of the discovery of the event, to the department and the patient's referring physician.

This bill would require instead a facility to report a CT X-ray irradiation ~~image examination~~ *that does not include the intended anatomic area area of the body if specified dose values are exceeded.* This bill would provide that reporting is not required if adjacent body parts are irradiated during the same treatment, unless specified *does values are exceeded.* This bill would ~~instead require that this report these reports be made within 10 business days of the discovery of the event~~ *5 business days of the discovery of a therapeutic event and within 10 business days of the discovery of a CT event.*

The bill would also make technical and clarifying changes.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes.
State-mandated local program: yes.

The people of the State of California do enact as follows:

SECTION 1. Section 115111 of the Health and Safety Code is amended to read:

115111. (a) Commencing July 1, 2012, subject to subdivision (e), a person that uses a computed tomography (CT) X-ray system for human use shall record the dose of radiation on every *diagnostic* CT study produced during a CT examination. CT studies used for therapeutic radiation treatment planning ~~or image guidance for interventional radiologic procedures or delivery~~ shall not be required to record the dose.

(b) The facility conducting the study shall ~~electronically~~ send *electronically* each CT study and protocol page that lists the technical factors and dose of radiation to the electronic picture archiving and communications system.

(c) (1) ~~The~~ *Until July 1, 2013, the* displayed dose shall be verified annually by a medical physicist for the facility's standard adult brain, adult abdomen, and pediatric brain protocols, to ensure the displayed doses are within 20 percent of the true measured dose measured in accordance with subdivision (f).

(2) A facility that has a ~~machine~~ *CT X-ray system* that is accredited *by an organization that is approved by the federal Centers for Medicare and Medicaid Services, an accrediting agency approved by the Medical Board of California, or the State Department of Public Health* may elect not to perform the verification described in paragraph (1).

(d) Subject to subdivision (e), the radiology report of a CT study shall include the dose of radiation by either recording the dose within the patient's radiology report or attaching the protocol page that includes the dose of radiation to the radiology report.

(e) The requirements of this section shall be limited to CT systems capable of calculating and displaying the dose.

(f) For the purposes of this section, dose of radiation shall be defined as one of the following:

(1) The computed tomography index volume (CTDI vol) and dose length product (DLP), as defined by the International Electrotechnical Commission (IEC) and recognized by the federal Food and Drug Administration (FDA).

(2) The dose unit as recommended by the American Association of Physicists in Medicine.

1 (g) For purposes of this section, “CT X-ray system” means the
2 same as provided in Section 892.1750 of Title 21 of the Code of
3 Federal Regulations.

4 SEC. 2. Section 115112 of the Health and Safety Code is
5 amended to read:

6 115112. Commencing July 1, 2013, CT X-ray systems shall
7 be accredited by an organization that is approved by the federal
8 Centers for Medicare and Medicaid Services, an accrediting agency
9 approved by the Medical Board of California, or the State
10 Department of Public Health.

11 SEC. 3. Section 115113 of the Health and Safety Code, as
12 amended by Section 1 of Chapter 139 of the Statutes of 2011, is
13 amended to read:

14 115113. (a) Except for an event that results from patient
15 movement or interference, a facility shall report to the department
16 an event in which the administration of radiation results in any of
17 the following:

18 (1) Repeating of a CT examination, unless otherwise ordered
19 by a physician or a radiologist, if one of the following dose values
20 are exceeded:

21 (A) 0.05 Sv (5 rem) effective dose.

22 (B) 0.5 Sv (50 rem) to an organ or tissue.

23 (C) 0.5 Sv (50 rem) shallow dose to the skin.

24 (2) A CT X-ray irradiation ~~image~~ examination that does not
25 include the intended ~~anatomic area~~ area of the body by the ordering
26 physician or a radiologist if one of the following dose values are
27 exceeded:

28 (A) 0.05 Sv (5 rem) effective dose.

29 (B) 0.5 Sv (50 rem) to an organ or tissue.

30 (C) 0.5 Sv (50 rem) shallow dose to the skin.

31 (3) CT or therapeutic exposure that results in unanticipated
32 permanent functional damage to an organ or a physiological
33 system, hair loss, or erythema, as determined by a qualified
34 physician.

35 (4) A CT or therapeutic dose to an embryo or fetus that is greater
36 than 50 mSv (5 rem) dose, that is a result of radiation to a known
37 pregnant individual unless the dose to the embryo or fetus was
38 specifically approved, in advance, by a qualified physician.

39 (5) Therapeutic ionizing irradiation of the wrong individual or
40 the wrong treatment site. Reporting is not required if adjacent body

1 parts are irradiated during the same treatment, unless they exceed
2 the values in paragraph (6) of this subdivision.

3 (6) The total dose from therapeutic ionizing radiation delivered
4 differs from the prescribed dose by 20 percent or more. A report
5 shall not be required pursuant to this paragraph in any instance
6 where the dose administered exceeds 20 percent of the amount
7 prescribed in a situation where the radiation was utilized for
8 palliative care for the specific patient. The radiation oncologist
9 shall notify the referring physician that the dose was exceeded.

10 (b) The facility shall, no later than *five business days after the*
11 *discovery of a therapeutic event described in paragraphs (3) to*
12 *(6), inclusive, of subdivision (a) and no later than 10 business days*
13 *after discovery of an event described in paragraphs (1) to (4),*
14 *inclusive, of subdivision (a),* provide notification of the event to
15 the department and the referring physician of the person subject
16 to the event and shall, no later than 15 business days after discovery
17 of an event described in subdivision (a) provide written notification
18 to the person who is subject to the event.

19 (c) This section shall become inoperative on the effective date
20 of the act that added this subdivision, and shall remain inoperative
21 until July 1, 2012.

22 SEC. 4. No reimbursement is required by this act pursuant to
23 Section 6 of Article XIII B of the California Constitution because
24 the only costs that may be incurred by a local agency or school
25 district will be incurred because this act creates a new crime or
26 infraction, eliminates a crime or infraction, or changes the penalty
27 for a crime or infraction, within the meaning of Section 17556 of
28 the Government Code, or changes the definition of a crime within
29 the meaning of Section 6 of Article XIII B of the California
30 Constitution.